

1 May 1968

Status of Draft of Principles Which Govern
Access to the Twin Registry

A draft of guidelines for access to the Twin Registry was developed by the staff as a result of recommendations made by the Committee at the last meeting. The draft was circulated for comment and review to Drs. Neel, De Bakey, Chalmers, and Moriyama. This subcommittee approved the enclosed draft in principle and suggested several modifications which have been incorporated in the attachment with a few minor editorial changes.

Several general questions have been raised which are not reflected in the enclosed draft. There has been concern about the control of information supplied to the investigators. With the passage of time might there be a tendency for investigators to develop a proprietary interest in subsamples from the panel and to initiate later studies on their own? There is a possibility of new investigators utilizing old files without knowledge of the arrangements under which they were obtained from NAS-NRC. In some instances it is possible to unlink individual identification from the data accumulated for a particular study, but this would be difficult to achieve in all studies.

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Principles Which Govern ~~Access to~~ the NAS-NRC Twin Registry

I. Introduction

The NAS-NRC Twin Registry, which includes some 16,000 pairs of white, male twins, all veterans of military or naval service in World War II, has been constructed and is maintained as a resource primarily intended for use in studies directed at elucidating environmental and genetic factors in the etiology of disease. Other applications are not excluded; however, all uses will be restricted to research studies. An example might be the use of identical twins to permit control of genetic factors while testing or assessing the effect of some extrinsic influences.

It is necessary to consider carefully each request for access to the members of the Registry or to the information accumulated concerning them, for a variety of reasons:

- (1) To safeguard the twins' privacy against unwarranted intrusion;
- (2) to determine that no embarrassment or harm will come to the twins by virtue of any particular study, either by unauthorized disclosure of confidential information or as a result of experimental manipulation;
- (3) to insure the scientific value and practicability of the study intended;
- (4) to protect members of the Registry from too frequent solicitation or from being subjected to conflicting demands by several investigators;
- (5) to coordinate the efforts of different investigators when this is feasible.

For the reasons enumerated above, every application for access to the Registry will be submitted for review to the Committee on Epidemiology and Veterans Follow-up Studies of the Division of Medical Sciences, National Research Council. Access will be granted only upon approval of the application by that Committee.

II. Specific Considerations

In addition to the requirement of scientific merit which is applicable to any research proposal, applications for access to the Twin Registry will be tested against a number of specific criteria:

If information is to be requested by mail:

- (1) Has an adequate time (~~ordinarily at least one year~~) elapsed since the last previous inquiry?

- (2) Do any of the questions proposed appear to duplicate too closely information already at hand?
- (3) Are any of the questions of such nature as to lead to possible alienation of the twins and their consequent loss for future investigations?
- (4) Are other proposals in hand or in clear prospect that could advantageously be combined with the request under study?
- (5) The applicant must agree that all mailings are to be done by the Registry itself, and that all information obtained will become a part of the Registry, for possible use by other investigators in the future. The Registry will, of course, make every effort to insure each investigator's rights to primacy in material collected for his own study, but no investigator will hold personal property rights in any data.

If physical examination of twins is required:

All of the considerations applicable to questionnaire studies apply. In addition:

- (6) Are any of the examination procedures proposed inherently risky to the patient without compensating advantages to the patient himself? Are any procedures painful or unpleasant and so likely to diminish future cooperation? Is the investigator adequately alert to the need to obtain the "informed consent" of each patient for all proposed procedures?
- (7) Initial solicitation of the twins shall be done by the Registry itself, and no names or addresses of twins shall be divulged to outside investigators except with the permission of the twins.
- (8) While not an absolute requirement, every investigator who establishes actual contact with twins will be expected, if possible, to arrange to obtain serum samples in order to improve zygosity diagnoses for those pairs in which laboratory diagnoses are not available. Genetic systems that should be tested include ABO, MN, Fy, Gm, Rh, P, Hp, Kell, Gc, Kidd, Lewis.
- (9) If twins are to be asked to visit a hospital or other place of examination rather than being themselves visited at home, the investigator must be prepared to defray ~~travel costs and per diem expenses~~. He must arrange, himself, to obtain the funds required for this purpose.

The examination is without cost to the twins.

S. O. B. A. T.

III. Financing

The Registry will be prepared, out of funds available to it under the contract with the National Institute of General Medical Sciences, to defray certain of the costs involved in planning and organizing studies. Such costs would ordinarily include compiling counts of the number or lists of twins who meet specified criteria, solicitation of agreements to participation in studies requiring examination and, to some extent, tabulations of results. Extraordinary expenses, such as those involved in a large questionnaire study, laboratory costs, travel costs or large tabulation requirements cannot be supported by the Registry and it is the responsibility of the applicant investigator to obtain the required financing.

Proposed studies should be submitted to review by the Committee prior to making any formal application for funds in order to avoid possible embarrassment. If funds are required for studies approved by the Committee, the Registry staff will, if desired, assist in the identification of sources of funds and, where appropriate, join in or otherwise support the application.

IV. Form of Application

The Committee's review is fundamentally no different from that of any other scientific review body which must evaluate research proposals. The Committee does not, primarily, dispose of funds. However, it does dispose of resources which are limited, and it must weigh the potential value of any proposal against the staff time and funds necessary to support it, and its real or potential competition with other proposals for whatever may be the budget of good will and willingness to cooperate which is inherent in the twin members of the Registry.

Although it need not necessarily be followed in detail, a satisfactory form of application is that of the Application for Research Grant used by the National Institutes of Health. The portions of this form which are relevant consist of:

1. Research Plan

- A. Introduction and Specific Aims
- B. Method of Procedure
- C. Significance of This Research
- D. Facilities Available

2. Supporting Data

- A. Previous Work Done in This or Related Fields
- B. Pertinent Literature References

3. Biographical Sketches of professional personnel who will be active in the study.

Included in item 1.B., if the application is so arranged, should be a discussion, when relevant, of questions of sample size and the possibility of answering, on the samples, the questions at issue, listed in item 1.A.

The application need not be long - prolixity will not be counted a virtue - but should be complete as to the relevant information which the Committee must have in order to decide intelligently.